# MENTORED QUANTITATIVE RESEARCH CAREER DEVELOPMENT AWARD (supercedes PA-99-087)

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National Institute of Mental Health

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National Institute of Neurological Disorders and Stroke

(http://www.ninds.nih.gov/)

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## PURPOSE OF THIS PA

A particular area of research is often invigorated by novel perspectives. In an effort to advance research relevant to the mission of the National Institutes of Health (NIH; which includes basic biomedical, clinical biomedical, bioengineering, bioimaging, and behavioral research), the participating Institutes and Centers solicit applications for the Mentored Quantitative Research Career Development Award (K25). The K25 mechanism is meant to attract to NIH-relevant research those investigators whose quantitative science and engineering research has thus far not been focused primarily on questions of health and disease. Examples of quantitative scientific and technical backgrounds considered appropriate for this award include, but are not limited to: mathematics, statistics, economics, computer science, imaging science, informatics, physics, chemistry, and engineering.

The K25 Award will support the career development of such investigators who make a commitment to basic or clinical biomedicine, bioengineering, bioimaging or behavioral research.

This award provides support for a period of supervised study and research for productive professionals with quantitative backgrounds who have the potential to integrate their expertise with NIH-relevant research and develop into productive investigators. It is intended for research-oriented investigators from the postdoctoral level to the level of senior faculty.

## RESEARCH OBJECTIVES

## Background

The NIH is especially interested in increasing the number of scientists trained to conduct high-quality research that combines insights derived from, and cuts across, different scientific, technical, and biomedical areas. Accordingly, this award forms an important part of an initiative to attract talented individuals with highly-developed quantitative skills to the challenges of research relevant to the mission of NIH. The Mentored Quantitative Research Career Development Award is intended to increase the availability of high-quality, multi-disciplinary, didactic training and research project guidance, in the context of a mentored research career transition, so that candidates interested in cross-disciplinary research will be well grounded in behavioral, biomedical, bioimaging, or bioengineering research. At the completion of the award, candidates should have both the knowledge and the skills necessary to compete for independent research support from NIH, or to participate as leading members of multi-disciplinary research teams. This initiative is consistent with the recommendations of the Bioengineering Education and Training Panel which was convened as part of the 1998 Bioengineering Consortium (BECON) Symposium (the symposium report is available at <a href="http://www.becon.nih.gov/becon\_symposia.htm">http://www.becon.nih.gov/becon\_symposia.htm</a>).

## Objectives and Scope

The objectives of the Mentored Quantitative Research Career Development Award (K25) are to:

o Encourage research-oriented quantitative scientists and engineers with little or no experience in biomedicine, bioengineering, bioimaging, or behavioral research to gain fundamental knowledge in these areas and develop relevant research skills, and to gain experience in current concepts, advanced methods, and experimental approaches that will allow them to conduct basic or clinical biomedical, behavioral, bioimaging, or bioengineering research, and to become independent investigators or play leading roles in multi-disciplinary research teams.

- o Increase the pool of quantitative researchers who can conduct biomedical, behavioral, or bioengineering studies, capitalizing on the quantitative backgrounds of the investigators to inform new directions in biomedical, behavioral and bioengineering research.
- o Provide a unique opportunity for candidates holding degrees in quantitative science or engineering to embark on three to five years of special study, including course work, seminars, meetings, and mentored research, to achieve the career enhancement goals outlined above.

Because of the focus on a progression toward independence as a quantitative biomedical, behavioral, bioimaging, or bioengineering researcher, the prospective candidate for the Mentored Quantitative Research Career Development Award will require enhanced skills in the experimental, theoretical and conceptual approaches used in biomedicine, behavioral science, bioimaging or bioengineering. To satisfy this requirement, the candidate should propose a period of study and career development that is complementary to her or his previous research and experience. For example, a candidate with no or very limited experience in a given field of biomedical research may find a phased developmental program lasting for five years that includes a designated period of didactic training together with a closely supervised research experience the most efficient means of attaining independence. A candidate with, for example, more research experience in biomedicine may benefit from a program with greater emphasis on appropriate laboratory research with lower levels of supervision and direction. All programs should be carefully tailored to meet the individual needs of the candidate and must include (an) active mentor(s) who is (are) competent and willing to provide the appropriate research guidance. Candidates should strongly consider incorporating into their training plan, formal courses in relevant areas of biomedicine, behavioral science, bioimaging, or bioengineering; this program offers a unique opportunity to devote protected time to this activity.

# MECHANISM OF SUPPORT

Awards in response to this program announcement will use the K25 mechanism. As an applicant, you and your mentor will be solely responsible for planning, directing, and executing the proposed project. The applicant institution must demonstrate its commitment to you and your goals for career development. The project period may be for up to five years with a minimum of three years. Awards are not renewable. K25 application instructions include "JUST IN TIME" streamlining efforts that postpone the collection of certain information until shortly before funding recommendations are made.

## Allowable Costs

A. Salary: The NIH will provide salary for up to 100% of the Principal Investigator's institutional base annual salary in any given year. Salary limits on career awards are not uniform throughout the NIH and are determined independently by each component of the NIH. Therefore, prospective candidates should contact the NIH component to which the application is targeted to ascertain the maximum contribution to the candidate's salary. None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of Executive Level I of the Federal Executive Pay Scale (for FY 2002, \$166,700/year; see <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-030.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-030.html</a>). The total salary requested must be based on a full-time, 12-month staff appointment and must be consistent both with the established salary structure at your institution and with salaries actually provided by the institution from its own or other non-federal funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

Your institution may supplement the NIH contribution up to a level consistent with the institution's salary scale. Supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. Because the salary amount provided by this award is based on the full-time institutional salary, no other NIH funds may be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with or detract from the purpose of the award.

Candidates must make a commitment of at least 75% effort to research and research career development activities of this award, and the remainder of the effort must be committed to other career development activities consistent with the overall purpose of the award.

- B. Research Development Support: The NIH will generally provide up to \$40,000 per year for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment, and technical personnel; c) travel to research meetings or training; and (d) research support services including personnel and computer time.
- C. Ancillary Personnel Support: Salary for mentors, secretarial and administrative assistance, etc., is not allowed.
- D. Facilities and Administrative costs: These costs will be reimbursed at 8 percent of modified total direct costs.

E. Other Income: Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation or other comparable activities, provided these activities remain incidental, are not required by the research and research-related activities of this award, and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

All other income and fees, not included in the preceding paragraph as retainable, may not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

- o The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.
- o The funds may be used for health-related research purposes.
- o The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.
- F. Special Leave: Leave to another institution, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed 3 months. For longer periods, prior written approval of the NIH funding component is required.

To obtain prior approval, you must submit a letter to the NIH describing the plan, countersigned by your department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH funding component and will be granted only in unusual situations. Support

from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

Under unusual and pressing personal circumstances, you may submit a written request to the awarding component requesting a reduction in professional effort below 75 percent. Such requests will be considered on a case-by-case basis during the award period. In no case will it be permissible to work at a rate of less than 50 percent effort. The nature of the circumstances requiring reduced effort might include medical conditions, disability, or pressing personal or family situations such as child or elder care. Permission to reduce the level of effort will not be approved to accommodate other sources of funding, job opportunities, clinical practice, or clinical training. In each situation, your institution must submit documentation supporting the need for reduced effort along with assurance of a continuing commitment to your scientific development. Further, you must submit assurance of your intention to return to full-time professional effort (at least 75 percent) as soon as possible. During the period of reduced effort, the salary and other costs supported by the award will be reduced accordingly.

G. Termination or Change of Institution: When a grantee institution plans to terminate an award, the NIH funding component must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination.

If you plan to relocate, you must submit to the NIH funding component, in advance of the move, a written request for transfer, countersigned by the appropriate institutional business official, describing the reasons for the change and including the new sponsor's name and biosketch. You must establish in this request that the specific aims of the research program to be conducted at the new institution are within the scope of the original peer reviewed research program.

Additionally, your new sponsor must have the appropriate research expertise to supervise your program and sufficient research support to ensure continuation of the research program to the end of the award. Staff within the NIH funding component will review this request and may require a review by an initial review group and/or the appropriate National Advisory Council or Board. Upon approval of the request, the new institution, on your behalf, must submit a new career award application far enough in advance of the requested effective date to permit review. The period of support requested in the new application must be no more than the time remaining within the existing award period.

When you plan to replace a mentor, the institution must submit a letter from the proposed mentor and awardee documenting the need for substitution, the new mentor's qualifications for

supervising the program, and the level of support for your continued career development. The letter must also document that the specific aims of the research program will remain within the scope of the original peer reviewed research program. Staff within the NIH funding component will review the request and will notify your institution of the results of the evaluation.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

If you have questions about any of these issues, please contact the appropriate NIH program staff person listed under "INQUIRIES."

## Awards Available

The actual number of awards to be made by each Institute will vary yearly and will depend upon the number and quality of applications submitted and funds available.

## **ELIGIBLE INSTITUTIONS**

You may submit an application if your institution is a domestic institution and has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government

# INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed career development program is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

Candidates must have an advanced degree in a quantitative area of science or engineering: M.S.E.E., Ph.D., D.Sc., etc. and have demonstrated research interests in their primary quantitative discipline. They must identify a mentor with extensive behavioral, biomedical, bioengineering, or bioimaging research experience. Candidates must make a commitment of at

least 75% effort to research and research career development and the remainder of the effort must be committed to other career development activities consistent with the overall purpose of the award.

Only U.S. citizens or noncitizen nationals, or an individual lawfully admitted for permanent residence who possesses an Alien Registration Receipt Card (I-151 or I-551), or some other verification of legal admission as a permanent resident, are eligible for this award. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Former principal investigators on NIH research project (R01), program project (P01), center grants, FIRST Awards (R29), sub-projects of program project (P01) or center grants, K01, K08 or K23 awards, or the equivalent are not eligible. Former principal investigators of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), or SBIR/STTR (R41, R42, R43, R44) remain eligible. A candidate for the Mentored Quantitative Research Career Development Award may not concurrently apply for any other PHS award that duplicates the provisions of this award nor have another application pending award. Mentored Quantitative Research Career Development Award recipients are strongly encouraged to apply for independent research grant support, either Federal or private, during the latter period of this K25 award. However, since the K25 is a full professional effort award, time conducting additional research directly related to this award is subsumed under the salary support already provided by this award.

The award is intended for investigators at any level of experience, from the postdoctoral level to senior faculty level, who have shown clear evidence of productivity and research excellence in the field of their training, and would like to expand their research capability, with the goal of making significant contributions to behavioral, biomedical (basic or clinical), bioimaging or bioengineering research.

NIGMS support for post-doctoral students using the K25 mechanism will be limited to certain areas of the basic biological sciences that fall within its mission. These include, but are not limited to bioinformatics, gene expression, signal transduction, pattern formation in embryogenesis, assembly and dynamics of macromolecular assemblies, cell division, metabolism, tissue- and organ-level homeostatic mechanisms, complex genetic traits, cell motility and mechanics, pharmacogenetics, and systemic host responses to trauma, burn, or other injury.

Specifically excluded are areas such as population biology, biophysics, biophysical chemistry, drug design, and structural biology, where theoretical and quantitative approaches are well established.

NIMH support for mentored career development awards is intended to assist new investigators at stages beyond postdoctoral training to gain additional supervised experience in order to become an independent scientist. Potential NIMH applicants are encouraged to review the NIMH K-award policy statement found at <a href="http://grants.nih.gov/grants/guide/notice-files/not-mh-02-001.html">http://grants.nih.gov/grants/guide/notice-files/not-mh-02-001.html</a> and to contact appropriate program staff prior to preparing an application.

## SPECIAL REQUIREMENTS

While each application is expected to be customized to the needs of the particular applicant, there are several elements which form the foundation for this career development award. The elements may take different forms for different candidates, but there are common aspects that will be considered carefully. These are described below:

- A. Candidate: The candidate should have demonstrated professional accomplishments consonant with his or her career status, and should have demonstrated experience or interest in pursuing research (including research outside of biomedicine, behavior, bioimaging, or bioengineering).
- B. Mentor(s): The recipient must receive appropriate mentoring throughout the duration of the program. Where feasible, women, minority individuals and individuals with disabilities should be involved as mentors and serve as role models. Candidates must name a primary mentor, who together with the applicant is responsible for planning, direction, and execution of the program. Candidates may also nominate additional secondary mentors as appropriate to the goals of the program.
- C. Program: The program provides up to five consecutive 12-month awards. At least 75 percent of the recipient's full-time professional effort must be devoted to research and research career development. The remainder must be devoted to clinical, teaching, or other research pursuits consistent with the career development objectives of the award.

Both the didactic and the research phases of an award period must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the career goals of the candidate.

D. Environment: The institution must have a well-established research and biomedical,

behavioral, or bioengineering career development program, or have demonstrable ties to such

programs. For example, if the mentor is based in industry and the career development program

requires didactic activities at a nearby university, access to such activities must be described.

The institution must also have individuals qualified in research to serve as mentors.

The institution must be able to demonstrate a commitment to the development of the candidate

as a productive, independent investigator. The candidate, mentor, and institution must be able to

describe an in-depth, multi disciplinary career development program (courses and research) that

will utilize the relevant research and educational resources (whether at the institution or at a site

with which there are demonstrable ties).

E. Evaluation: In carrying out its stewardship of human resource-related programs, the NIH may

request information essential to an assessment of the effectiveness of this program. Accordingly,

recipients are hereby notified that they may be contacted after the completion of this award for

periodic updates on various aspects of their employment history, publications, support from

research grants or contracts, honors and awards, professional activities, and other information

helpful in evaluating the impact of the program.

WHERE TO SEND INQUIRIES

We strongly encourage your inquiries concerning this program announcement, especially during

the planning phase of the application, and welcome the opportunity to answer questions from

potential applicants.

o DIRECT YOUR QUESTIONS ABOUT SCIENTIFIC/RESEARCH ISSUES TO ONE OF THE

FOLLOWING INDIVIDUALS, BASED ON YOUR AREA OF SCIENTIFIC INTEREST:

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o DIRECT YOUR QUESTIONS ABOUT FINANCIAL OR GRANTS MANAGEMENT MATTERS

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## SUBMITTING AN APPLICATION

Potential applicants are strongly encouraged to contact the staff person in the relevant institute or center listed under INQUIRIES. Such contact should occur early in the planning phase of application preparation. Contacting a staff person will help ensure that applications are responsive to the goals and policies of the individual institute or center.

Applicants who will be using a General Clinical Research Center (GCRC) are requested to include a letter of agreement from either the GCRC program director or the principal investigator with the application.

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at

http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format.

You must follow the additional instructions for Research Career Awards within the 398 instructions and forms. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <a href="http://grants.nih.gov/grants/dates.htm">http://grants.nih.gov/grants/dates.htm</a>. Application deadlines are also indicated in the PHS 398 application kit. At the time this PA was issued, these deadlines were February 1, June 1 and October 1.

To identify the application as a response to this program announcement, check "YES" on item 2 of page 1 of the application and enter "PA-02-127 MENTORED QUANTITATIVE RESEARCH CAREER DEVELOPMENT AWARD."

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application with Checklist, and five signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW

NATIONAL INSTITUTES OF HEALTH

6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710

BETHESDA, MD 20892-7710

BETHESDA, MD 20817-7710 (for express/courier service)

The title and number of this program announcement must be typed on line 2 of the face page of the application form and the YES box must be marked.

APPLICATION PROCESSING: Applications must be received by, or mailed on or before, the receipt dates described at <a href="http://grants.nih.gov/grants/funding/submissionschedule.htm">http://grants.nih.gov/grants/funding/submissionschedule.htm</a>. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such an application must include an Introduction addressing the previous critique.

The application must contain the following information:

## Candidate

- o A description of the candidate's commitment to a career in quantitative biomedical, bioimaging, behavioral, or bioengineering research.
- o Evidence of the candidate's interest in conducting research.
- o Evidence of the candidate's potential to develop into a successful independent investigator. Usually this is evident from publications, prior research interests and experience, and letters of recommendation.

- o A description of the candidate's immediate and long-term career objectives, explaining how the award will contribute to their attainment.
- A commitment of at least 75 percent effort to this research program. The mentor or department chair must agree that this amount of the candidate's time will be protected.
- o Letters of recommendation: Three sealed letters of recommendation addressing the candidate's potential for a research career in quantitative biomedicine or bioengineering must be included as part of the application. The mentor's statement (see below) should not be included as one of the letters of recommendation, although the mentor(s) may submit a separate letter(s) of recommendation.

## Career Development Plan

- o A description of the career development plan, incorporating consideration of the candidate's goals and prior experience. A systematic plan to obtain the necessary theoretical and conceptual background and research experience to launch an independent research career in quantitative biomedicine, bioengineering, bioimaging or behavioral research must be proposed.
- o A list of the specific course of study in which the candidate will engage, including specific coursework which is essential to gaining the required theoretical and conceptual understanding of biomedicine, behavioral science, bioimaging, or bioengineering, important to the candidate's short- and long-term research interests and the manner of integration of these studies into the career development plan.
- o The career development plan must be tailored to the needs of the individual candidate and the ultimate goal of achieving independence as a researcher in quantitative biomedicine, behavioral science, bioimaging, or bioengineering. Less experienced candidates may require a phased developmental period in which the first one to two year(s) of the award are largely of a didactic nature followed by a period of intense, supervised research. Candidates with more experience at the time of application may need a shorter developmental period and may already have an adequate theoretical background.

Training in the Responsible Conduct of Research

o Candidates must describe plans to receive instruction in the responsible conduct of research. These plans must detail the proposed subject matter, format, frequency, and duration of instruction. No award will be made if an application lacks this component.

#### Research Plan

o Describe the quantitative biomedical, behavioral, or bioengineering research plan. The research plan must be described as outlined in form PHS 398, including sections on the Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Research Design and Methods. The candidate should confer closely with the mentor(s) regarding the development of these sections.

## Mentor's Statement

- o The application must include a statement from the mentor(s), including information on his or her basic or clinical biomedical research qualifications in the research area proposed by the candidate and previous experience as a research supervisor. The application must also include information to describe the mentor's research support relevant to the candidate's research plan and the nature and extent of supervision that he/she will provide during the period of the award. The primary mentor must agree to provide annual evaluations of the trainee's progress for the duration of the award. Mentors may be employed in any sector of the biomedical research community (e.g., academia, industry, non-profit research institutions).
- o Similar information must be provided by each co-mentor. When more than one mentor is proposed, the respective areas of expertise and responsibility of each should be described.

# **Environment and Institutional Commitment**

o The institution must have a strong, well-established research program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration. The institution also must provide a statement to document the level of commitment to the candidate's development into a productive, independent investigator during the period of the award. This must include an indication of support for the proposed level of effort (at least 75 percent), commitment to the necessary release time from other duties (e.g. teaching), as well as the availability of support and supervision during the award period.

# **Budget Instructions**

o Budget information must be provided according to the instructions in the PHS 398, including information on the mentor(s)' pending and current research support as stipulated. The total direct costs requested must be consistent with this K25 program announcement and the award limits of the NIH funding component. Applicants seeking information on award limits should contact the likely funding component listed in the INQUIRIES section.

## PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened by the individual Institute in accordance with the standard NIH peer review procedures (<a href="http://www.csr.nih.gov/refrev.htm">http://www.csr.nih.gov/refrev.htm</a>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Receive a written critique
- o Receive a second level review by the appropriate national advisory council or board

## **REVIEW CRITERIA**

The following review criteria will be applied:

## Candidate

- o Quality of the research and academic record;
- o Potential to develop as an independent quantitative biomedical or bioengineering researcher or to play a significant role in multi-disciplinary research teams; and
- o Commitment to a career in quantitative biomedical or bioengineering research.

# Career Development Plan

 Likelihood that the career development plan will contribute substantially to the candidate's scientific development;

- o Appropriateness of the content and duration of the proposed didactic and research phases of the award; and
- o Consistency of the career development plan with the candidate's career goals and prior research experience.

Training in the Responsible Conduct of Research

o Quality of the proposed training in responsible conduct of research.

#### Research Plan

Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Although it is understood that K25 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- o Appropriateness of the research plan to the candidate's stage of research development and as a vehicle for developing the research skills as described in the career development plan;
- o Scientific and technical merit of the research question, design and methodology;
- o Relevance of the proposed research to the candidate's career objectives; and
- o Adequacy of the plans to include both genders, minorities, and children and their subgroups as appropriate for the scientific goals of the research when human subjects are used. Plans for the recruitment and retention of subjects will also be evaluated, when applicable.

#### Mentor

- o History of research productivity and support in the area of basic or clinical biomedical, bioengineering, bioimaging or behavioral research;
- o Appropriateness of the mentor's research qualifications in the area of this application;

- o Quality and extent of the mentor's proposed role in providing guidance and advice; and
- o Previous experience in fostering the development of researchers.

Institutional Environment and Commitment

- o Evidence that the institution is committed to the candidate's scientific development and assurance that the institution intends for the candidate to be an integral part of its research program;
- Adequacy of research facilities and training opportunities (including access to such facilities or opportunities in other institutions);
- o Quality and relevance of the environment for the candidate's scientific and professional development; and
- o Institution's commitment to an appropriate balance of research and other responsibilities.

# Budget

o The requested budget must be appropriate in relation to the candidate's career development goals and research aims and plans.

## AWARD CRITERIA

Applications will be assigned to an Institute based on referral guidelines. The Institute will notify the applicant of the Advisory Board or Council's action shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and Advisory Council/Board, the need for research personnel in specific program areas, and the availability of funds.

# REQUIRED FEDERAL CITATIONS

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose

of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH
Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research
- Amended, October, 2001," published in the NIH Guide for Grants and Contracts on
October 9, 2001 (<a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html</a>); a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women min/guidelines amended 10 2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

All investigators proposing research involving human subjects should read the policy that was published in the NIH Guide for Grants an Contracts, June 5, 2000 (Revised August 25, 2000), and is available at the following URL address <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html</a>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at <a href="http://grants.nih.gov/grants/stem\_cells.htm">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html</a>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <a href="http://escr.nih.gov/">http://escr.nih.gov/</a>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: <a href="http://grants.nih.gov/grants/policy/a110/a110\_guidance\_dec1999.htm">http://grants.nih.gov/grants/policy/a110/a110\_guidance\_dec1999.htm</a>.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

EVALUATION: In carrying out its stewardship of human resource related programs, the NIH may begin requesting information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <a href="http://www.health.gov/healthypeople">http://www.health.gov/healthypeople</a>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance Nos. 93.394 (NCI); 93.233, 93.837, 93.838, 93.839 (NHLBI); 93.172 (NHGRI); 93.866 (NIA); 93.271 (NIAAA); 93.846 (NIAMS); 93.286, 93.287 (NIBIB); 93.929 (NICHD); 93.173 (NIDCD); 93.121 (NIDCR); 93.849, 93.848 and 93.847 (NIDDK); 93.277 (NIDA); 93.114 (NIEHS); 93.821, 93.859, 93.862 (NIGMS); 93.281 (NIMH); 93.853 (NINDS); and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284 and administered under NIH grants policies described at <a href="http://grants.nih.gov/grants/policy/policy.htm">http://grants.nih.gov/grants/policy/policy.htm</a> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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